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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/974,753 | 10/09/2001 | Alan J. Schroit | UTSC:594USD1/MBW | 8205 |

7590 08/27/2003

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| EXAMINER | |
|---|---|
| NICKOL, GARY B | |
| ART UNIT | PAPER NUMBER |
| 1642 | 9 |

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/974,753 | SCHROIT, ALAN J. | |
| | Examiner | Art Unit | |
| | Gary B. Nickol Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28,29 and 37-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49-54* is/are allowed.

6)☒ Claim(s) *28,29,38-40 and 42-48* is/are rejected.

7)☒ Claim(s) *37 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

***Response to Amendment***

The Amendment filed June 23, 2003 (Paper No. 8) in response to the Office Action of March 20, 2003 is acknowledged and has been entered.

Claims 30-36 were cancelled.

Claims 37-54 were added.

Claims 28-29, and 37-54 are pending and are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Withdrawn:**

The rejection of Claims 28-31 under 35 U.S.C. 102(b) as being anticipated by Bate *et al.* (Immunology, Vol. 79, 1993, pages 138-145, IDS) is withdrawn in view of applicant's submission of the inventor's Declaration filed under 37 CFR 1.132 in Paper No. 8.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

**New Rejections:**

Claims 42-48 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a phosphatidylserine/polypeptide conjugate composition that is "**not a phosphatidylserine/KLH conjugate composition**" has no clear support in the specification and the claims as originally filed. Applicants state (Paper No. 8,page 4) that support for the newly amended subject matter is found in the claims as originally filed and throughout the specification. However, the suggested support is not found persuasive because there is nothing in the specification to suggest the negative limitation of "not a phosphatidylserine/KLH conjugate composition".

If applicant should disagree with this rejection, applicant should submit evidence pointing to the serial number, page and line where support can be found for the disputed terminology.

Claims 28-29, 38, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamamura *et al.* (Japan. J. Exp. Med. Vol 41, 1 pages 31-38, 1971, IDS).

Tamamura *et al.* teach a method of making an antibody that specifically binds to phosphatidylserine comprising administering to an animal a pharmaceutical composition comprising an immunologically effective amount of a phosphatidylserine/polypeptide conjugate composition wherein the pharmaceutical composition comprises a phosphatidylserine/BSA conjugate. Specifically, Tamamura *et al.* teach (abstract, Table 1, and discussion) a method of administering to an animal an immunologically effective amount of PS-MBSA (phosphatidylserine/*methylated* bovine serum albumin) to elicit antibodies that specifically bind to phosphatidylserine. For the purposes of comparing the claims to the prior art, it is noted that the specification does not specifically define the limitations of what is included or excluded by

the phrase "phosphatidylserine/polypeptide conjugate composition". For example, the specification teaches (page 14, 2nd paragraph) that with respect to preparing lipid-specific antibodies, it is necessary to boost the host immune system, and *may* be achieved by coupling the lipid of interest, such as PS, to a carrier. Hence, it appears that the PS-MBSA composition of Tamamura *et al.* is a lipid/polypeptide conjugate composition because the lipids and MBSA are joined together in a composition. Further, since claims 29 and 43 are drawn to pharmaceutical compositions *comprising* PS/BSA- the methylated conjugate composition of Tamamura broadly comprises BSA, albeit in a methylated form. Furthermore, it appears that Tamamura *et al.* broadly teach detection of the antibodies via immunoelectrophoresis with anti-rabbit-IgG (page 32) which reads on detectable labeling of the antibody.

Claims 28, 38-40, 42, and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Maneta-Peyret *et al.* (Jnl. Immunological Methods, Vol. 108, 1988, pages 123-127, IDS).

Maneta-Peyret *et al.* teach a method of making an antibody that specifically binds to phosphatidylserine comprising administering to an animal a pharmaceutical composition comprising an immunologically effective amount of a phosphatidylserine/polypeptide conjugate composition wherein the pharmaceutical composition comprises a phosphatidylserine/cytochrome C conjugate composition. Again, as set forth above, the specification does not specifically define what is meant by a "conjugate". Thus, the claims are broadly interpreted as a composition comprising phosphatidylserine joined with cytochrome C. Maneta-Peyret *et al.* further teach immunological methods for detecting the antiphosphatidylserine antibodies including ELISA assays (page 124, 2nd column).

Claims 37 and 41 are objected as being dependent from a rejected base claim.

Claims 49-54 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 26, 2003